

FORM PTO -1083

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450



Docket No.: 300.1005CON  
Date: April 10, 2006

# 71w

In re application of: Chih-Ming CHEN, et al.  
Serial No.: 10/796,411  
Filed: March 9, 2004  
For: **CONTROLLED RELEASE METFORMIN COMPOSITIONS**

Sir:

Transmitted herewith is a **Supplemental Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
- ☐ Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
- ☒ No fee for additional claims is required.
- ☐ A filing fee for additional claims calculated as shown below, is required:

☒ Also transmitted herewith are:

☐ Petition for extension under 37 C.F.R. 1.136

☒ Other:- **Form PTO-1449 (2 sheets) and copies of references cited therein**

☒ Check(s) in the amount of **\$180.00** is/are attached to cover:

☐ Filing fee for additional claims under 37 C.F.R. 1.16

☐ Petition fee for extension under 37 C.F.R. 1.136

☒ Other: **Information Disclosure Statement Fee**

☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

☐ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.

☒ Any patent application processing fees under 37 C.F.R. 1.17.

☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
Robert J. Paradiso, Reg. No. 41,240  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on April 10, 2006.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: 

**UNITED STATES PATENT & TRADEMARK OFFICE**

Re: Serial No.: 10/796,411  
 Application of: Chi-Ming Chen, et al.  
 Filed: December 27, 2004  
 For: **Controlled Release Metformin Compositions**  
 Art Unit: 1615  
 Docket No.: 300.1005CON  
 Customer No.: 23280

Mail Stop: Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

April 10, 2006

**SUPPLEMENTAL INFORMATION DISCLOSURE**  
**STATEMENT UNDER 37 C.F.R. § 1.56**

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (2 sheets) for consideration by the Examiner in connection with the examination of the above-identified patent application.

In accordance with 37 C.F.R. § 1.98 (a)(2), copies of the references listed in the FOREIGN PATENT DOCUMENTS and OTHER PRIOR ART REFERENCES sections of the accompanying Form PTO-1449 are enclosed. If it is determined that a copy of any of the listed references is not presently enclosed, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

Applicants also respectfully advise the Examiner of the following co-pending U.S. patent applications which are commonly assigned to the owners of the instant application:

04/18/2006 WASFAW1 00000139 10796411

01 FC:1806

180.00 OP

U.S. Patent Application Serial No. 11/117,999, "Controlled Release Metformin Compositions," filed April 29, 2005, published on February 16, 2006 as U.S. Publication No. 2006/0034922, listed as reference "BF" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 09/726,193, "Controlled Release Metformin Compositions," filed November 29, 2000, published on September 27, 2001 as U.S. Publication No. 2001/0024659, listed as reference "BL" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/225,741, "Controlled Release Metformin Compositions," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008525, listed as reference "BG" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/224,784, "Controlled Release Metformin Compositons," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008523, listed as reference "BI" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/224,785, "Controlled Release Metformin Compositions," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008524, listed as reference "BH" on the enclosed Form PTO-1449;

U.S. Patent Application Serial No. 11/225,742, "Controlled Release Metformin Compositions," filed September 13, 2005, published on January 12, 2006 as U.S. Publication No. 2006/0008526, listed as reference "BJ" on the enclosed Form PTO-1449;

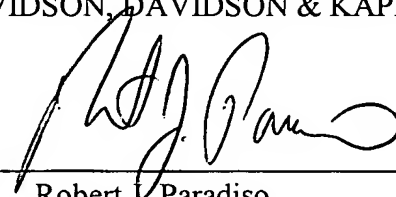
U.S. Patent Application Serial No. 10/442,692, "Biguanide formulations," filed May 20, 2003, published on March 18, 2004 as U.S. Publication No. 2004/0052848, listed as reference "BK" on the enclosed Form PTO-1449.

It is respectfully requested that the reference cited in the accompanying Form PTO-1449 (2 sheets) be considered and made of record.

This Information Disclosure Statement is being filed after a First Office Action but before a Final Office Action or Notice of Allowance. Pursuant to 37 C.F.R. § 1.98(c), a check for \$180.00 is enclosed to cover the required fee. However, if it is determined that any additional fee is due or an overpayment has been made, the Examiner is authorized to charge said fee or credit said overpayment to our Attorney Deposit Account No. 50-0552.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By



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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
300.1005CON

SERIAL NO.: 10/796,411

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): CHEN et al.

FILING DATE: March 9, 2004

GROUP: 1615

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA						

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
AB							

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AC	Approval letter from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 000, October 13, 2000
AD	Approved Label for Glucophage/Glucophage XR, NDA 21-202, Supplement 000, October 13, 2000
AE	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 003, January 8, 2002
AF	Approval letter on formulation revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 008, April 11, 2003
AG	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 011, March 19, 2004
AH	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 013, March 19, 2004
AI	Approval letter on labeling revision from Center for Drug Evaluation and Research to Bristol-Myers Squibb Company on NDA 21-202, Supplement 001, April 19, 2001
AJ	Approved Label For Glucophage/Glucophage XR NDA 21-202, Supplement 013, March 19, 2004
AK	Approved Label for Glucophage/Glucophage XR NDA 21-202, Supplement 011, March 19, 2004
AL	Approved Label for Glucophage/Glucophage XR NDA 21-201, Supplement 008, labeling revision, April 11, 2003
AM	
AN	
AO	
AP	
AQ	
AR	
AS	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 300.1005CON		SERIAL NO.: 10796,411								
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>				APPLICANT(S): CHEN et al.										
(Use several sheets if necessary)				FILING DATE: March 9, 2004		GROUP: 1615								
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	BA	5	9	1	4	3	2	6	06/22/99	McCarty et al.	514	188		
	BB	6	1	1	7	4	5	1	09/12/00	Kumar	424	465		
	BC	5	1	0	0	6	5	9	03/31/92	Hyon, et al.	424	426		
	BD	5	8	3	7	9	7	9	11/17/98	Chen et al.	424	465		
	BE	6	0	5	9	9	7	7	05/02/00	Bhagwat et al.	424	488		
	BF	20	06	00	34	9	2	2	02/16/06	Cheng et al.				
	BC	20	06	00	08	5	2	5	01/12/06	Chen et al.				
	BH	20	06	00	08	5	2	4	01/12/06	Chen et al.				
	BI	20	06	00	08	5	2	9	01/12/06	Chen et al.				
	BJ	20	06	00	08	5	2	6	01/12/06	Chen et al.				
	BK	20	04	00	52	8	4	9	03/18/04	Cheng et al.				
	BL	20	01	00	24	6	9	9	09/27/01	Chen et al.				
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BM	2	2	9	1	4	3	9	02/28/00	CA	A61K	31/44		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	BN	E.K. Kastrop: "Anidiabetic Agents," DRUG FACTS AND COMPARISONS, 1999, St. Louis, pp 635-642												
	BO	Physicians' Desk Reference, "Glucophage XR," 56 <sup>th</sup> edition, pages 1080-1086												
	BP	Physicians' Desk Reference, "Glucophage," 52 <sup>nd</sup> edition, pages 795-800												
	BQ	STN Registry Search for Metformin												
	BR													
	BS													
EXAMINER										DATE CONSIDERED				
<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>														